UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)))))))) MDL No. 2419) Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO:	
All Suits Against the Saint Thomas Entities))
)

MEMORANDUM IN SUPPORT OF THE SAINT THOMAS ENTITIES' MOTION TO COMPEL MEDICAL SALES MANAGEMENT TO PRODUCE TRAINING AND MARKETING MATERIALS

Pursuant to Federal Rules of Civil Procedure 26, 33, 34, 36, and 37, the Saint Thomas Entities¹ hereby file this motion to compel Medical Sales Management, Inc. and Medical Sales Management SW, Inc. (collectively "MSM") to produce certain materials in response to the Saint Thomas Entities' First Set of Interrogatories, Requests for Production, and Requests for Admission.² The Saint Thomas Entities also file this motion to compel certain readily identifiable documents that are in MSM's possession, custody or control. In light of the Court's denial of the Saint Thomas Entities' motion to compel all documents produced to MSM's owners, directors and managers by the United States as being overly broad, the Saint Thomas Entities have provided MSM an updated, narrow list of highly relevant and readily identifiable

54133260.1 - 1 -

¹ Saint Thomas West Hospital f/k/a St. Thomas Hospital; Saint Thomas Health; and Saint Thomas Network.

² Although counsel for the Saint Thomas Entities and MSM are currently working cooperatively in developing search terms to guide MSM's production of documents, the Saint Thomas Entities reserve the right to compel production from MSM in the even that it becomes necessary. MSM's Objections, Answers and Responses to the St. Thomas Entities' First Set of Interrogatories, Requests for Production, and Requests for Admission, attached as Exhibit A.

items. For the reasons explained in this Memorandum, this Court should compel MSM to produce the materials discussed below.

I. BACKGROUND AND SUMMARY OF ARGUMENT

This litigation stems from an outbreak of fungal meningitis due to the contamination of pharmaceutical products compounded by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center. ("NECC"). Plaintiffs made claims against numerous parties other than NECC, including the Saint Thomas Entities and Saint Thomas Outpatient Neurosurgical Center ("STOPNC").³ STOPNC, like thousands of health care providers across the country, did nothing more than purchase medication from NECC to administer to patients. The Saint Thomas Entities have been sued because one of them (Saint Thomas Network) owns half of STOPNC. It is uncontested that neither the Saint Thomas Entities nor STOPNC had *any role whatsoever* in causing the contamination. Nor is there any evidence that the Saint Thomas Entities or STOPNC had any knowledge of any contamination by NECC.

The Saint Thomas Entities asserted that certain persons and entities, including MSM, caused or contributed to the injuries and deaths at issue in this lawsuit.⁴ MSM's officers and directors include Douglas Conigliaro, Barry Cadden, and Gregory Conigliaro, who are also founders and/or directors of NECC.⁵ Douglas Conigliaro is an owner of MSM. In marketing NECC's products, MSM falsely stated that the NECC facility and its products were compliant with all required industry standards, were of high quality and had been tested for sterility. Evidence from MSM and its sales force, including items related to marketing strategies and

54133260.1 - 2 -

³ See Mem. of Decision [re: Motions to Dismiss] at p. 3 (Dkt. No. 1360).

⁴ See Saint Thomas Entities' Master Answer [Dkt. No. 1464].

⁵ See Business Entity Summary, Medical Sales Management, Inc., attached hereto as Ex. B.

representations made to customers, is needed so that the jury may properly conclude that MSM proximately caused plaintiffs' injuries.

Pursuant to Magistrate Judge Boal's order on the Saint Thomas Entities' motion to enforce a court order permitting comparative fault discovery, in April of 2015, the Saint Thomas Entities requested documents from MSM that are highly relevant to their claims.⁶ Specifically, the Saint Thomas Entities requested:

- All training materials used by MSM regarding advertising, selling, or distributing compounded medications, including but not limited to MPA; and
- All marketing and advertising materials used by MSM to market compounded medications or compounding services for NECC or Ameridose.⁷

MSM refused to produce any training documents or videos responsive to the Saint Thomas Entities' requests.

The Saint Thomas Entities subsequently learned that a significant amount of MSM training materials, including audio and video recordings, had been seized by the Government and returned to MSM's owners and directors as part of criminal discovery. Accordingly, the Saint Thomas Entities moved to compel the individuals to produce all materials provided to them by the Government in *United States v. Cadden et al.*, No. 1:14-cr-10363-RGS.⁸ Those documents included the training materials and records that were responsive to the Saint Thomas Entities' requests for production to MSM.

54133260.1 - 3 -

⁶ See Order Granting Motion for Order to Enforce Court Order Permitting Comparative Fault Discovery [Dkt. No. 1797].

⁷ See Exhibit A, Requests for Production Nos. 7 and 10.

⁸ Saint Thomas Entities' Motion to Compel Invoking Defendants to Produce Certain Documents (Dkt. Nos. 2117-18).

On September 10, 2015, Judge Boal denied the Saint Thomas Entities' motion to compel. Although she acknowledged that some of the documents sought by the Saint Thomas Entities would be relevant, Judge Boal stated that the Saint Thomas Entities' blanket request for all 8.7 million documents was overly broad and failed to demonstrate particularized need for the materials.

In light of Judge Boal's Order, the Saint Thomas Entities have narrowed their request to the materials listed below, all of which are responsive to the document requests cited above.

II. ARGUMENT AND AUTHORITY

A. Legal Authorities

Federal Rule of Civil Procedure 26(b)(1) provides:

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding *any nonprivileged matter that is relevant to any party's claim or defense*—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. All discovery is subject to the limitations imposed by Rule 26(b)(2)(C).

The United States Supreme Court has further held that the limits set forth in Rule 26 must be "construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case."

In addition, Federal Rule of Civil Procedure 34(a) states:

A party may serve on any other party a request within the scope of Rule 26(b): (1) to produce and permit the requesting party or its representative to inspect, copy, test, or sample the following items in the responding party's possession, custody, or control: (A) any designated documents or electronically stored information—including writings, drawings, graphs, charts, photographs, sound

54133260.1 - 4 -

⁹ Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 (1978).

recordings, images, and other data or data compilations—stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form; or (B) any designated tangible things; . . .

B. This Court Should Order MSM to Produce Marketing and Training Materials, Including Those Returned Through Criminal Discovery

The items requested by the Saint Thomas Entities in their requests for production are relevant and discoverable. MSM falsely represented to NECC's customers that the NECC facility and its products were safe, tested and compliant with industry standards. The Saint Thomas Entities requested documents related to the training provided to MSM employees regarding advertising, selling, or distributing pharmaceuticals; as well as marketing and advertising materials used by MSM to market compounded medications or compounding services for NECC or Ameridose. Such materials sought from MSM and its sales force, including items related to MSM's marketing strategies and representations made to customers, are clearly relevant. As such, the Saint Thomas Entities respectfully request that this Court compel production of documents responsive to Document Requests 7 and 10, listed above.

These two requests cover any materials that were returned to MSM's owner, directors and managers as a result of criminal discovery. In particular, the Saint Thomas Entities seek:

- Twenty-six discs containing audio and video recordings of NECC sales trainings labeled "NECC Sales Audio and Video.";
- White binder labeled, in part, "NECC Sales & Product Training March 7-11, 2005" (Control # 56);
- Compact discs labeled, in part, "Barry Cadden Sales Education" (Control # 56);
- Compact disks labeled, in part, "Barry Cadden Sales Education" (Control # 28);
- Compact Discs labeled, in part, "Barry Cadden Sales Education" (Control # 41);
- Pages of instructions on confirming orders (Control # 27);
- White binder labeled, in part, "New England Compounding Center Pharmacy and Product Training Guide" (Control # 6);

54133260.1 - 5 -

- Packet labeled, in part, "Do you have questions about specific risk levels for any of your hospital's compounded preparations?" {Control # 43);
- Promotional book labeled, in part, "NECC Hospital" (Control # 15);
- White binders labeled, in part, "Training Binder" (Control # 33);
- White binders labeled, in part, "Hospital Team Training Binder" (Control # 33); and
- White binder labeled, in part, "necc Surgery Center Training Binder" (Control # 8);
- White binder labeled, in part, "necc Surgery Center Training Binder" (Control # 7); and
- White binders labeled, in part, "Surgery Center Training Binder" (Control #33).

These documents are relevant and discoverable business records that are unquestionably in MSM's possession, custody, and control. *See Flagg v. City of Detroit*, 252 F.R.D. 346, 353 (E.D. Mich. 2008) (A corporate party may be deemed to have control over documents in the possession of one of its officers or employees.); *Riddell Sports, Inc. v. Brooks*, 158 F.R.D. 555 (S.D.N.Y. 1994) (Corporate party to a lawsuit could be compelled to produce items in possession of one of its officers); Fed. R. Civ. P. 34(a) (A party must produce requested documents that are in that party's "possession, custody or control.").

Moreover, none of these materials could possibly be protected from disclosure by the protective order in the criminal action, which only applies to patient or financial information. And MSM has no Fifth amendment right protecting its business records. *See, e.g., United States v. Lawn Builders of New England*, 856 F.2d 388, 393 (1st Cir. 1988) ("It is well-settled that a corporation has no Fifth Amendment privilege to refuse to produce corporate records."). Furthermore, there is no Fifth Amendment privilege against producing in civil litigation what the government already possesses. *See eBay, Inc. v. Digital Point Solutions, Inc.*, 2010 U.S. Dist. LEXIS 7997 (N.D. Cal. 2010). For these reasons, this Court should compel MSM to produce the training and marketing materials that have been requested, including the narrow list of business

54133260.1 - 6 -

records listed above that were itemized in the Government's discovery letters in the criminal action.

III. CONCLUSION

WHEREFORE, the Saint Thomas Entities respectfully request the Court for an order compelling MSM to:

- Produce the marketing and training materials requested by the Saint Thomas Entities (Requests No. 7 and 10); and
- produce the narrow set of readily identifiable documents that the United States produced to MSM, which relate to the training of MSM employees, as well as MSM and NECC's marketing strategies.

LOCAL RULE 37.1 CERTIFICATION

Counsel for the Saint Thomas Entities met and conferred with counsel for MSM in a good-faith effort to resolve this discovery dispute but no resolution was reached.

54133260.1 - 7 -

Dated: September 14, 2015

By their attorneys,

/s/ Sarah P. Kelly

Sarah P. Kelly (BBO #664267) skelly@nutter.com

NUTTER McCLENNEN & FISH LLP Seaport West 155 Seaport Boulevard Boston, Massachusetts 02210 (617) 439-2000 (617) 310-9461 (FAX)

OF COUNSEL:

Yvonne K. Puig*
Texas State Bar No. 16385400
yvonne.puig@nortonrosefulbright.com
Adam T. Schramek*
Texas State Bar No. 24033045
adam.schramek@nortonrosefulbright.com
Eric J. Hoffman*
Texas State Bar No. 24074427
eric.hoffman@nortonrosefulbright.com

NORTON ROSE FULBRIGHT US LLP 98 San Jacinto Blvd., Suite 1100 Austin, Texas 78701 (512) 536-2450 (512) 536-4598 (FAX)

Marcy Hogan Greer*
Texas State Bar No. 08417650
mgreer@adjtlaw.com

ALEXANDER DUBOSE JEFFERSON & TOWNSEND LLP 515 Congress, Suite 2350 Austin, Texas 78701 (512) 482-9300 (512) 482-9303

54133260.1 - 8 -

^{*}Appearing Pro Hac Vice

CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing this 14^{th} day of September, 2015.

/s/ Sarah P. Kelly
Sarah P. Kelly

2882640.1

54133260.1 - 9 -